



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2015-N-0002]

New Animal Drugs for Use in Animal Feed; Withdrawal of Approval of New Animal Drug Applications; Nitarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new animal drug applications (NADAs) providing for the use of nitarsone in medicated feed for chickens and turkeys. This action is being taken at the sponsor's request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective December 31, 2015.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following NADAs that provide for the use of nitarsone in medicated feed for chickens and turkeys because the products are no longer manufactured or marketed:

File No.	Product Name	21 CFR Section
007-616	HISTOSTAT 50 (nitarsone) Type A Medicated Article	558.369

File No.	Product Name	21 CFR Section
141-088	HISTOSTAT 50 (nitarstone)/BMD (bacitracin methylene disalicylate)	558.369
141-132	HISTOSTAT 50/ALBAC (bacitracin zinc)	558.369

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with 21 CFR 514.116 Notice of withdrawal of approval of application, notice is given that approval of NADAs 007-616, 141-088, and 141-132, and all supplements and amendments thereto, is hereby withdrawn, effective December 31, 2015.

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: December 11, 2015.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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